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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,349	08/20/2003	Richard A. Shimkets	15966-557 PO (CURA 57 PO)	5850
55111	7590	05/17/2006	EXAMINER	
MINTZ, LEVIN, COHN, FERRIS, GLOVSKY & POPEO, P.C. ONE FINANCIAL CENTER BOSTON, MA 02111			SAOUD, CHRISTINE J	
			ART UNIT	PAPER NUMBER
			1647	
DATE MAILED: 05/17/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/644,349	SHIMKETS, RICHARD A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 20 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>04/01/05</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of Group IX, claims 19, 20 and 25, drawn to methods of treating a hyperphosphatemic condition by administering FGF20 polypeptides in the reply filed on 15 February 2006 is acknowledged.

Claims 1-18, 21-24 and a portion of claim 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 15 February 2006.

Claim 25 is directed to the claimed invention as well as administration of "a reagent that increases the level of FGF20 polypeptide". Claim 25 was also included in Group X based on this limitation. Group X is a non-elected invention, therefore, claim 25 should be amended so that it no longer contains a non-elected invention.

### ***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The information disclosure statement (IDS) submitted on 01 April 2005 is in compliance and has been considered by the Examiner. An initialed and signed copy of the IDS should accompany this Office action.

### ***Specification***

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The disclosure is objected to because of the following informalities: Example 7 of the Specification at page 17-18 is not in compliance with 37 CFR 1.821(d) which requires the use of a sequence identifier when making reference to a sequence even if it is embedded in the text of the description of the patent application.

Appropriate correction is required.

Applicant should note that page 3 of the specification is illegible because the left portion of the page did not copy. This error could be at the PTO level (i.e. problems in the scanning process) or it could be at the time the application was filed (i.e. copying problems). Applicant should review their files in the event that the error was in the copying process. The PTO is currently making sure that page 3 which has been scanned is identical to the image in our computer system. Please just indicate in response to this Office action whether page 3 in your files is complete. If it is not, please file a replacement page as an amendment to the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 20 is a method of treatment by administration of a polypeptide wherein "the FGF20 polypeptide comprises a mutation that confers increased stability to said FGF20 polypeptide". However, there is no disclosure in the instant specification regarding instability of FGF20 or ways to modify FGF20 which would increase stability. The specification does not discuss stability of FGF20 or the amino acid sequence of FGF20 in such a way as to point out any particular amino acids which would affect stability. The art does not recognize that FGF20 is a protein that is inherently unstable or a protein that is in need of stabilization, or identify amino acids which should be mutated in order to increase stability. The art does not recognize the FGF family in general as a protein family that is in need of stabilization, nor teach that FGF proteins should contain mutations at corresponding positions to increase stability of the molecules. Furthermore, the claim does not identify what kind of stability is intended, nor does the specification identify what type of stabilization would be intended. There is a lack of

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disclosure for what type of mutation is encompassed by the claims, there are no working examples, and there is no structure – function relationship provided. Therefore, the specification contains subject matter which was not described in such a way as to reasonably convey to one skilled in the relevant art at the time the application was filed, that the inventor was in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-20 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are directed to a method of treating a condition involving increased levels of phosphate by administration of “FGF20”. However, the mere recitation of the term “FGF20” does not convey the actual nature of the molecule being administered. This is because in the art of proteins and growth factors, the naming of particular molecules does not follow any precise rules such that one of skill in the art could be assured that the protein being called “FGF20” is not another researcher’s FGF21 or FGF-XYZ or FGF-nov, etc. Therefore, without some recitation of the actual structure or nature of the molecule which is being used in the method, the claims are indefinite because it is not clear what is included or excluded by the term “FGF20”. The metes and bounds of the claims cannot be determined.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD  
PRIMARY EXAMINER  
*Christine J. Saoud*